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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,256	10/09/2001	Gyorgy Lajos Kis	OP/4-30969A/N1/CVH21	6198

1095 7590 01/21/2004

THOMAS HOXIE  
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

EXAMINER

NICOLAS, FREDERICK C

ART UNIT PAPER NUMBER

3754

DATE MAILED: 01/21/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/973,256

Applicant(s)

KIS ET AL.

Examiner

Frederick C. Nicolas

Art Unit

3754

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 34-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 34-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vlasich 5,048,727 in view of Czaplinski et al. 3,709,365.

Vlasich discloses a pharmaceutical package as seen in figure 1, which comprises a closed polypropylene bottle/barrel (12) in which is disposed a solution (15), the solution comprises a pharmaceutical product (col. 2, ll. 57-64), wherein the solution does not fill the bottle completely and some air is disposed in the bottle (col. 3, ll. 34-39). Vlasich lacks after autoclaving the package at at least 121°C and for at least 20 minutes, suffers no deformation, does not shrink, and does not explode and where the package retains a sufficiently high squeezability to dispense the solution. Czaplinski et al. teach the use of autoclaving a polypropylene material at about 115°-125°C. from 20-30 minutes (col. 2, ll. 49-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Vlasich's package by autoclaving the package, as taught by Czaplinski et al. in (col. 2, ll. 49-58), in order to treat a material that can withstand autoclaving at a temperature 121°C for at least 20 minutes.

As to claim 41, lines 1-3, the claimed subject matter "wherein physical properties of said polypropylene meet requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3<sup>rd</sup> edition (1997).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Vlasich's package as such, in order to comply with the requirements of the European Pharmacopoeia, 3<sup>rd</sup> edition (1997), as such is notoriously well known in the art.

With respect to claim 35, Vlasich discloses that the package further comprises a plastic nozzle tip (14) for dispensing the solution and a cap (17) for closing the bottle, wherein the bottle has walls that have a wall-thickness as seen in Figures 1-2.

With respect to claim 36, Vlasich discloses that the bottle comprises a neck portion (14b) that includes an externally threaded portion and an outer rim (19) which defines an outlet of the bottle, wherein the nozzle tip is in fluid contact with the outlet of the bottle as seen in Figure 2, wherein the nozzle tip has a dispensing pathway in fluid communication with an outlet, and wherein the cap has an internal threads for engagement with the externally threaded portion of the neck of the bottle (col. 4, ll. 11-15 and as seen in Figure 1).

As to claim 37, the claimed subject matter "the bottle is made of Appryl 3020 SM 3, the nozzle tip is made of Appryl 3020 SM 3, and the cap is made of HDPE GC 7260.

At the time the invention was made, It would have been an obvious matter of design choice to a person of ordinary skill in the art to have made Vlasich's bottle and nozzle tip of Appryl 3020 SM 3, and the cap of HDPE GC 7260, because applicant has not disclosed that the bottle is made of Appryl 3020 SM 3, the nozzle tip is made of Appryl 3020 SM 3, and the cap is made of HDPE GC 7260, provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with Vlasich's bottle, nozzle tip and cap, because Vlasich's bottle, cap and nozzle tip form an enclosed container.

Therefore, it would have been an obvious matter of design choice to modify Vlasich's bottle, cap and nozzle tip to obtain the invention specified in claim (37).

With respect to claim 38, Vlasich discloses that the bottle has a bottom portion see Figure 1 for location, where the bottom portion of the bottle has a concave configuration as seen in Figure 1.

As to claim 39, the claimed subject matter, the bottle has a wall-thickness in the range of 0.3 mm to 0.6 mm, as well as the claimed subject matter in claim 40.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Vlasich's wall-thickness as such, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering

the optimum or workable ranges involves only routine skill in the art. As per MPEP 2144.05

As to claim 42, lines 1-3, the claimed subject matter "wherein physical properties of said polypropylene meet requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3<sup>rd</sup> edition (1997).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Vlasich's package as such, in order to comply with the requirements of the European Pharmacopoeia, 3<sup>rd</sup> edition (1997), as such is notoriously well known in the art.

### ***Response to Arguments***

3. Applicant's arguments filed 11/26/2003 have been fully considered but are moot in view of the new ground(s) of rejection. Any remaining arguments have been fully addressed in the above rejection.

### ***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick C. Nicolas whose telephone number is (703)-305-6385. The examiner can normally be reached on Monday - Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mancene L Gene, can be reached on (703) 308-2696. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

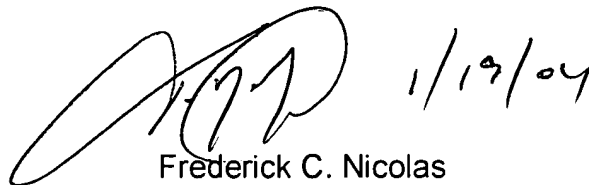
Application/Control Number: 09/973,256

Page 6

Art Unit: 3754

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0861.

FN  
January 19, 2003

A handwritten signature in black ink, appearing to be 'F. Nicolas', is written over the printed name. To the right of the signature, the date '1/19/04' is handwritten.

Frederick C. Nicolas  
Patent Examiner  
Art Unit 3754